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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/517,704 | 08/30/2005 | Gerd Dahms | BPD-0014 | 9138 |
| 23413 | 7590 | 10/03/2008 | EXAMINER | |
| CANTOR COLBURN, LLP | | | HOLT, ANDRIAE M | |
| 20 Church Street | | | ART UNIT | PAPER NUMBER |
| 22nd Floor | | | 1616 | |
| Hartford, CT 06103 | | | | |
| NOTIFICATION DATE | | DELIVERY MODE | | |
| 10/03/2008 | | ELECTRONIC | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

usptopatentmail@cantorcolburn.com

| | | |
|------------------------------|--------------------------------------|------------------------------------|
| Office Action Summary | Application No. 10/517,704 | Applicant(s) DAHMS, GERD |
| | Examiner Andriae M. Holt | Art Unit 1616 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 04 June 2008.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 17-21 and 23 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 17-21 and 23 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO-1668)
 Paper No(s)/Mail Date _____

4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____

5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

Claims 17-21 and 23 are pending in the application. The examiner acknowledges Applicant's remarks regarding claims "pending" in the previous Office Action. The examiner also acknowledges and affirms that the previous ground of rejection was a 103 (a) Obviousness Rejection over Mather et al. and Nagashima et al.

Rejections not reiterated from the previous Office Action are hereby withdrawn. The following rejections are newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 17-21 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mather et al. (WO 96/39119) in view of Martino et al. (US 5,011,630).

Applicant's Invention

Applicant claims an ether alcohol/polyol-in-oil emulsion comprising at least one ether alcohol of the general formula (I) $R_1-O-[EO]_n-H$ where R_1 is C1-3-alkyl, n is on average 7 to 15, and EO is building blocks derived from ethylene oxide, in an oil-

immiscible ether alcohol/polyol phase, an oil phase and at least one emulsifier.

Applicant further claims that a cosmetic and/or pharmaceutical and/or agrochemical active ingredient is dissolved in the ether alcohol/polyol phase.

**Determination of the scope of the content of the prior art
(MPEP 2141.01):**

Mather et al. teach the invention relates to topical compositions containing azelaic acid and glycol and more particularly to new and improved compositions containing stabilized and completely solubilized azelaic acid (page 1, lines 7-10). Mather et al. further teach that another objective is to provide lower, yet effective concentrations of a topical azelaic acid formulation that is less likely to irritate the skin of the user (page 5, lines 5-7). Mather et al. teach that azelaic acid, a straight chain dicarboxylic acid with 9 carbons, has limited solubility in water and commonly used cosmetic oils. Mather et al. teach that low levels of azelaic acid may be completely dissolved in glycol from about 20% (w/w) to about 60% (w/w) (claim 20, 50 % weight, instant invention) and remain in stable solution (page 4, lines 20-25). Mather et al. teach that the glycol utilized may be one or more of the following, including methoxypolyethylene glycol (page 4, lines 25-28) (ether alcohol, methanol ethoxylate, claims 17 and 20, instant invention).

Mather et al. teach on page 8, in example 3, lines 15-34, that an emulsion with commonly used cosmetic oils is made by mixing azelaic acid with dipropylene glycol and distilled water, which the mixture is then heated to 70° C until a clear solution results (claim 21, comprises a pharmaceutical active, instant invention). Mather further teaches that in a separate container C12-C15 benzoate, isododecane, cyclomethicone,

stearyl alcohol (claim 17, emulsifier, instant invention), a commercial mixture of glyceryl stearate and PEG-100 stearate (ARLACEL 165) and a commercial mixture of isopropylparaben, isobutylparaben and butylparaben (LIQUAPAR OIL)(claim 17, oil, instant invention). Mather et al. teach that to this mixture the azelaic acid-dipropylene glycol-water mixture is added and the whole mixed while maintaining the temperature at 70° C. Mather et al. further teach the mixture is allowed to cool to 45° C.

**Difference between the prior art and the claims
(MPEP 2141.02)**

Mather et al. do not teach the use of the specific ether alcohol of general formula (I), wherein the number of ethylene oxide units is 7. It is for this reason Martino et al. is joined.

Martino et al. teach a water dispersible, self-emulsifiable triglyceride composition which comprises the reaction of a) an addition product of a triglyceride oil of an unsaturated fatty acid having at least 12 carbon atoms (claim 17, oil, instant invention) and b) a water soluble compound selected from the group consisting of a monohydroxy- or monoamino-terminated blocked polyalkylene oxide and mixtures thereof (claim 17, compounds of formula (I), instant invention) (col. 2, lines 9-23). Martino et al. teach the triglyceride oils used are the glycerol esters of both conjugated and unconjugated fatty acids, including corn oil, sunflower oil, etc. (col. 2, lines 29-41). Martino et al. teach the novel water dispersible, self-emulsifiable compounds of the present invention are prepared by the esterification or amidification of the triglyceride oil/olefinic-acid (or anhydride) addition product by a blocked polyalkylene oxide compound which contains

only one reactive (i.e., hydroxyl or amino) group capable of reacting with the acid or anhydride moiety of the triglyceride product. Martino et al. further teach that the polyalkylene oxide units, which may be the same or a mixture of different alkylene oxides, comprise alkylene units of 2 to 5, preferably 2 to 3, carbon atoms. Martino et al. teach that particularly useful are water soluble polyoxyethylene compounds having molecular weights of about 300 to 2700 which are often utilized as nonionic surfactants. Martino et al. further teach the number of ethylene oxide units can range from about 7 to about 60, preferably 8 to 17 (col. 3, lines 53-68) (claims 17-19, ethylene oxide units 7 to 15).

Martino et al. teach in example 5, col. 6, lines 60-68, that samples of the corn oil addition products of Examples 1 and 2 were esterified with 30% PEGMME 750 according to the procedure of Example 3. Martino et al. teach that the reaction data and dispersibility test results of the products is be found in Table II. Martino et al. further teach in example 6, col. 7, lines 18-55, the effects of the molecular weight of the hydrophilic reagents. Martino et al. teach that as can be seen by the results, the polyalkylene oxides useful are those having molecular weights greater than about 300. Martino et al. further teach that in terms of repeating ethylene oxide units, only compounds having 7 or more repeating units provide products which are both water dispersible and self-emulsifiable. The acronym, PEGMME in Table III, represents polyethylene glycol monomethyl ethers, which are compounds of formula (I) of the instant application essentially having 7 or more ethylene oxide units.

**Finding of obviousness/Rationale and Motivation
(MPEP 2142-2143)**

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of the two cited references and use specific ether alcohol of general formula wherein the number of ethylene oxide units is 7 in the compositions as taught by Mather et al. Mather et al. teach it is within the skill of one skilled in the art to use glycol derivatives to prepare emulsions containing a pharmaceutical agent, particularly methoxypolyethylene glycol, which is in the general class of ether alcohols represented by compounds of formula I. One would have been motivated to use methoxypolyethylene glycol with a reasonable expectation of success since Mather et al. teach methoxypolyethylene glycol and dipropylene glycol can be used as the glycol in azelaic acid compositions. Therefore, it would have been *prima facie* obvious to substitute one glycol such as methoxypolyethylene glycol for another glycol such as dipropylene glycol since the prior art establishes methoxypolyethylene glycol and dipropylene glycol are all functional equivalents.

Furthermore, Martino et al. teach that polyalkylene oxides, PEGMME, also known in the art as methoxypolyethylene glycol, that have repeating ethylene oxide units of 7 or more provide products that are both water dispersible and self-emulsifiable. Therefore, one skilled in the art at the time the invention was made would have been motivated to use methoxypolyethylene glycol, PEGMME, with ethylene oxide units of 7, with a reasonable expectation of success to produce a water dispersible and self-

emulsifiable composition that decreases skin irritation in cosmetics or pharmaceutical active.

Therefore, the claimed invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made because every element of the invention has been fairly suggested by the cited references.

None of the claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDRIAE M. HOLT whose telephone number is (571)272-9328. The examiner can normally be reached on 7:00 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richter Johann can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Andriae M. Holt
Patent Examiner
Art Unit 1616

/John Pak/
Primary Examiner, Art Unit 1616